CLAIMS

1. A method for the stabilization of the pharmaceutical active solid substance atorvastatin alone or in a mixture with other solid substances embedded in a gaseous mixture characterized in that in the surrounding gaseous mixture a partial pressure of oxygen of at most 2 kPa is maintained.

2. The method according to claim 1 characterized in that the partial pressure of oxygen is maintained lower than 1 kPa.

3. The method according to claim 1 characterized in that the partial pressure of oxygen is maintained lower than 0.4 kPa.

4. The method according to claims 1-3 characterized in that atorvastatin is in a mixture containing solid magnesium oxide in an amount of 0.1 to 50 % by weight.

5. The method according to any of the preceding claims characterized in that atorvastatin is predominantly in an amorphous form.

6. The method according to claims 1-5 characterized in that the method stabilizes a drug in the form of tablets or capsules containing atorvastatin in an amount of 1 to 60 % by weight.

7. The method according to claim 6 characterized in that the drug is packaged in a blister.

8. The method according to claim 7 characterized in that the blister is an aluminium blister of the Al-Al type.

9. The method according to claim 7 characterized in that the drug is packaged in a polypropylene blister, which is further enveloped in an Al-Al pouch.

10. The method according to claim 6 characterized in that the drug is packaged in a strip.

11. The method according to any of the preceding claims characterized in that the said partial pressure is achieved by use of at least one oxygen absorber.

12. The method according to claim 11 characterized in that the oxygen absorber is selected from the group including a humidity-activated oxygen absorber, a self-activating absorber, an ultraviolet-radiation-activated absorber, a radiation-activated absorber, a microwaves-activated absorber, an absorber activated by a combination of activation processes, or an absorber without necessity of activation.

13. The method according to claim 12 characterized in that the oxygen absorber is a self-activating absorber.

14. The method according to any of claims 1–10 characterized in that the said partial pressure is achieved by use of excess of an inert gas.

15. The method according to any of claims 6-9 and 14 characterized in that the said partial pressure is achieved by packaging in a blister-forming machine, by introducing a stream of an inert gas, preferably nitrogen, into cavities in the lower shaped sheet with such intensity that the content of the gas in the cavity exchanges at least once, preferably three times.

16. The method of claim 15 characterized in that the flow rate of the inert gas ranges from 180 to 3000 l/h.

17. The method of claim 16 characterized in that the flow rate of the inert gas ranges from 500 to 1500 l/h.

18. The method according to any of claims 15-17 characterized in that the band with shaped cavities is brought into a purging chamber, consisting of a set of nozzles, destined for targeted introduction of the inert gas to the cavities, and of diversion channels for the washed-out air outlet, the purging chamber being located in a box having permanently inert atmosphere, wherein, subsequently, an upper covering band is pressed against said band with the cavities and, finally, the blister is welded together.

19. The method according to claim 15 characterized in that the flow rate of the inert gas into the purging chamber is maintained at 1300 – 1500 l/h.

20. The method according to any of claims 1-10 characterized in that the said partial pressure is achieved by packaging under a pressure of 0.3 to 10 kPa.

21. A pharmaceutical composition in a pharmaceutically suitable packing comprising a blister, obtainable according to claim 19, surrounded with a gaseous mixture constituted by the inert gas fed during the packaging, characterized by a partial pressure of oxygen lower than 1 kPa.

22. The pharmaceutical composition according to claim 21, characterized by a partial pressure of oxygen lower than 0.4 kPa.

23. A pharmaceutical composition obtained by a method of any of claims 1-20 characterized in that it is constituted by 3 - 20 % by weight of atorvastatin, 5 - 30 % by weight of magnesium oxide, 5 - 30 % by weight of lactose, and 20 - 80 % by weight of microcrystalline cellulose.